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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,499	07/26/2001	David Hung	05284.00096	6261

22907 7590 07/18/2002

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EXAMINER

ASSADI, KATHRYN L

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,499

Applicant(s)

HUNG, DAVID

Examiner

Kathryn L Assadi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a device for collection of breast duct fluid, classified in class 604, subclass 1.
- II. Claims 14-21, drawn to a method of collection and analysis of breast duct fluid, classified in class 604, subclass 28.
- III. Claim 22, drawn to a system of collection and analysis of breast duct fluid, classified in class 600, subclass 578.
- IV. Claims 23-24, drawn to an article for collection of breast duct fluid, classified in class 604, subclass 74.
- V. Claim 25, drawn to a method of collection and analysis of breast duct fluid, classified in class 604, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as infusion of medicament to the breast duct lumen.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a probe of any size can be used to access of any part of the breast duct. The subcombination has separate utility such as insertion of a probe with a diameter sufficiently small to access the interior lumen of the breast duct.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. For example, the probe as claimed in Claim 1 is inserted inside the human body to contact the interior lumen of a breast duct for collection of fluid. On the other hand, the article as claimed in Claim 23 is not inserted into the human body, but used to collect breast duct fluid from the surface of the nipple.

Inventions I and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP §

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806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus such as a breast pump.

Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as infusion of medicament to the breast duct lumen.

Inventions II and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as infusion of medicament on the surface of the nipple.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. For example, the method as claimed in Claim 14 uses a probe that is inserted into the lumen of the breast duct, whereas the method as claimed in Claim 25 uses a receiving unit that comes in contact with the surface of the nipple.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. For example, the system as claimed in Claim 22 comprises a probe that is inserted inside the human body to contact the interior lumen of a breast duct for collection of fluid. On the other hand, the article as claimed in Claim 23 is not inserted into the human body, but used to collect breast duct fluid from the surface of the nipple.

Inventions III and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as infusion of medicament to the breast duct lumen.

Inventions IV and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as topical cleansing of pores.

During a telephone conversation with Mr. Brian E. Hanlon on June 6, 2002 a provisional election was made without traverse to prosecute the invention of Group I,

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claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-25 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 rejected under 35 U.S.C. 102(b) as being anticipated by Kremer (US 4,635,488). Kremer teaches a device for collection of breast duct fluid and detection of breast cancer or precancer comprising a probe, absorbent material on the distal portion of the probe, a tubular collection portion, the distal portion comprising a surface having molecules affixed that bind an agent in the ductal fluid it contacts, a means to measure the quality of the ductal fluid *in situ* (Figure 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer in view of Hung et al (US 6,413,228). Kremer teaches all of the claimed limitations except a quality of the ductal fluid comprises an indicia or marker. Hung et al

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discloses a quality of the ductal fluid that comprises an indicia or marker (Page 3, [0021]). Hung et al teaches that the cellular material that is collected from a human breast milk duct is a substance selected from the group consisting of whole cells, cellular debris, proteins, nucleic acids, polypeptides, glycoproteins, lipids, fats, glycoproteins, small organic molecules, metabolites, and macromolecules. It would have been obvious to one with ordinary skill in the art to use the teachings of Hung et al to modify the invention of Kremer to create a device for collection of breast duct fluid that analyzes the different substances found in the ductal fluid.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer in view of MacDonald et al (US 5,844,251). Kremer teaches all of the claimed limitations except a probe comprising MEMS. MacDonald et al discloses a probe wherein the distal portion comprises a MEMS (Column 2, Lines 52-67). MacDonald et al teaches that the MEMS on the probe is used in scanning tunneling microscopes, atomic force microscopes, mechanical positioning, as a magnetic field, electric field, capacitance, or van den Waals force detector. It would have been obvious to one with ordinary skill in the art to use the teachings of MacDonald et al to modify the invention of Kremer in order to create a probe with a MEMS that is used to scan surfaces of the breast duct to measure surface configurations on the micron scale.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer in view of Wilk (US 5,263,926). Kremer teaches all of the claimed limitations except a probe that comprises a coating of an anesthetic on its exterior. Wilk teaches a probe that comprises a coating of an anesthetic on its exterior (Column 7, Lines 56-63). Wilk

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discloses that the anesthetic is applied on the exterior of the probe so that immediate temporary relief may be provided after completion of treatment. It would have been obvious to one with ordinary skill in the art to use the teachings of Wilk to modify the invention of Kremer to create a probe with anesthetic on its outer surface to provide the patient with relief from possible discomfort due to treatment.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer in view of Nita et al (US 5,382,228). Kremer teaches all of the claimed limitations except a probe that comprises a shape memory material and is rigid before entry into the breast duct and flexible upon residence in the duct. Nita et al teaches a probe (24) with shape memory material (Column 6, Lines 32-34) that becomes more flexible during its time spent in the body. Nita et al discloses that devices made of shape memory material exhibit superelasticity consistently within the range of temperatures normally encountered during operation of the device. It would have been obvious to one with ordinary skill in the art to use the teachings of Nita et al to modify the invention of Kremer to create a probe that can change elasticity and become more flexible during its operation in the breast duct.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Assadi whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLA

June 15, 2002

KLA

Michael J. Hayes

**MICHAEL J. HAYES
PRIMARY EXAMINER**